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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/335,363 06/17/99 SHIBATA

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EXAMINER

BEX, P

ART UNIT

PAPER NUMBER

1743

DATE MAILED:

04/16/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

# Office Action Summary

Application No.

09/335,363

Applicant(s)

SHIBATA ET AL.

Examiner

P. K. Bex

Art Unit

1743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 22 January 1999.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-32 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 June 1999 is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4.
- 18) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

## DETAILED ACTION

### *Drawings*

1. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character "44" has been used to designate both sample tube and tube identification station, see page 11, lines 5-14. Correction is required.

### *Specification*

2. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: the specification does not support the limitation of immediate storage tube location with an associated alert mechanism for identifying when the immediate sample is loaded into the system, see claims 11 and 24. The specification does support error flagging when a sample identification is not stored in the DataLink Computer, see page 22, lines 4-7. In claim 1, lines 9-10, recite the use of sample tube transfer station adapted to move a *sample* tube from the continuous transport mechanism, this recitation is not clear. The specification support the removal of a *reaction vessel* or *secondary tube* from the continuous transport mechanism, see page 8, lines 8-14 and page 18, para 2.

### *Claim Rejections - 35 USC § 112*

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1, line 4, "sample tube" should be --primary sample tube -- for consistency. Same deficiency was found in line 6.

Lines 9-10, recite the use of sample tube transfer station adapted to move a *sample* tube from the continuous transport mechanism. It is unclear as to whether applicant meant for the *sample tube* to be removed from the continuous transport mechanism or the *secondary* or *reaction vessel* is to be removed from the continuous transport mechanism. The instant specification recites the removal of a *reaction vessel* or *secondary tube* from the continuous transport mechanism, see page 8, lines 8-14 and page 18, para 2. For examination purposes, Examiner has interpreted that Applicant intended the filled *secondary tubes* to be removed from the continuous transport mechanism. The same deficiency was found in claims 20 and 27-32.

Line 10, "the continuous transport mechanism" lacks antecedent basis.

Claim 20, line 3, "a carriage mechanism that transports samples" is vague and indefinite. How are the samples transported? It is suggested that "samples" be replaced with --sample tubes--. This will provide proper antecedent basis for "sample tubes" in line 4 of the claim.

Claim 22, line 2, "indirectly" control is indefinite. It is not clear as to how the controller controls "indirectly" controls the determination of the sample identification information. Clarification is requested.

### ***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 20-23, 25-30 are rejected under 35 U.S.C. 102(b) as being anticipated by Mazza *et al* (USP 5,350,564).

Mazza *et al* teach a automated analyzer system comprising a sample identification station for determining sample identification information, a carriage mechanism 16, 22 that transports sample tubes 28 with a bar code 30 to the sample identification station 234, a continuous transport mechanism 10 for moving the sample tubes within the system. Wherein, the continuous transport mechanism is a continuous belt 248 with a plurality of sample tube carriages 32 mounted on thereon. The sample tube carriages hold the sample tubes in place with resilient clips 258 and provide lateral access to the tube from at least two sides of the sample tube (Figs. 8-9). The system further comprising a plurality of tube transfer stations 48 adapted to move a sample tube from the continuous transport mechanism to an interface 42 of a plurality of analyzers 40, a controller "C" for receiving sample identification information and issuing a sample testing procedure (Figs. 1-10).

### ***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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8. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. Claims 1-11, 13-19, 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mazza *et al* (USP 5,350,564) in view of Kodama *et al* (USP 6,117,683).

Mazza *et al* as discussed previously, fail to teach a carriage mechanism that grips one of the plurality of primary sample tubes and transports the primary sample tubes to a sampling station or the sampling station including a probe that draws a volume of sample from a sample tube and transfers the volume to a reaction tube. Kodama *et al* do teach a carriage mechanism 15b that grips a rack containing a plurality of primary sample tubes and transports the primary sample tubes to a sampling station 16b wherein, the sampling station includes a probe 204 that draws a volume of sample from a sample tube and transfers the volume to a reaction tubes in reaction conveyer 203. Moreover, Kodama *et al* teach an alert mechanism 33 for identifying when an immediate sample tray is loaded into the system (column 4, lines 28-40) and a control unit, 1, conveyance instructing unit and operation unit.

Accordingly, it would have obvious to one of ordinary skill in the art to modify the automatic analyzer of Mazza *et al* with those of Kodama *et al* at the time of the claimed invention. One skilled in the art would have recognized the benefits of using an intermediate

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sample probe to dispense sample to a plurality of reaction tubes, thereby reducing the amount of limited sample needed for analysis.

Regarding the specific location of the clips within the sample tube carriage, Mazza *et al* discloses the claimed invention except for the use of clips that engage the upper and lower portion of the sample tube. It would have been an obvious matter of design choice to include such use of clips. Moreover, since applicant has not disclosed that the location of the clips solves any stated problem or is for any particular purpose and it appears that the invention would perform equally well with the clips taught by Mazza *et al*.

10. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mazza *et al* (USP 5,350,564) and Kodama *et al* (USP 6,117,683) as applied to claim 10, and further in view of Kurosaki *et al* (USP 5,587,129).

Mazza *et al* and Kodama *et al* as discussed previously, fail to teach a sample probe comprising a cap piercer for removing liquid from the primary sample without removing the cap from the primary sample tube. However, the use of cap piercing probes is considered conventional in the art, see Kurosaki *et al*. Kurosaki *et al* teach an automatic analyzer which comprises a probe 12 for aspirating part of a sample from a sample tube 4 and dispensing into a reaction tubes 8 (column 3, line 62- column 4, line 7).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have incorporated in the system of Mazza *et al* and Kodama *et al* the piercing probe, as taught by Kurosaki *et al*, in order to aspirate the contents of the sample vial without exposing the sample to possible environmental contaminants.

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**Conclusion**


11. No claims allowed.
12. The prior art made of record and not relied upon is considered pertinent to applicant's disclose are Boje *et al*, Babson *et al*, Kawaguchi *et al*, Ishihara *et al*, Riggs, Buhler *et al*, O'Bryan *et al*, Saito *et al* and Koreyasu *et al*. They are cited of interest in that they show various embodiments of automated analyzer with conveyers and carriage mechanisms.
13. Any inquiry concerning this communication or earlier communications form the examiner should be directed to P. Kathryn Bex whose telephone number is (703) 306-5697.

The fax number for the organization where this application or proceeding is assigned is (703) 305-7718 for official papers prior to mailing of a Final Office Action. For official papers after mailing of a Final Office Action, use fax number (703) 305-3599. For unofficial or draft papers use fax number (703) 305-7719. Please label all faxes as official or unofficial. The above fax numbers will allow the paper to be forwarded to the examiner in a timely manner.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0661.



P. Kathryn Bex  
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4/10/01



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